

DETAILED ACTION

1. Applicant's amendment and remarks filed 2/22/11 are acknowledged.
2. Claims 3-13, 15, 17, 23, 25, and 31 stand withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected inventions/species.

Claims 1 and 14 are being acted upon.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claim 1 stands rejected under 35 U.S.C. 102(b) as anticipated by Arunachalam et al. (2000).

Arunachalam et al. teaches a peptide comprising the amino acid sequence of SEQ ID NO:49 and sequences selected for SEQ ID NOs:1-3 (see particularly Figure 1A.).

The reference clearly anticipates the claimed invention.

Applicant argues that the instant amendment overcomes the rejection.

Applicant is advised that the combination of "comprising" and "consisting of" in the same claim is reasonably considered to comprise open claim language, i.e., reading on the whole protein. Should Applicant wish to claim a specific fragment of the amino acid sequence of SEQ ID NO:1 Applicant should amend the claims accordingly.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the

Art Unit: 1644

differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 14 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Arunachalam et al. (2000) in view of Jüsten et al. (2000) and Godkins et al. (2001).

Arunachalam et al. has been discussed above.

The reference teaching differs from the claimed invention only in that it does not teach a peptide comprising the amino acid sequence of SEQ ID NO:49 further comprising an MHC Class II molecule.

Jüsten et al. (2000) teaches that in their search for genes and gene products that might be involved in the pathogenesis of rheumatoid arthritis (RA) they found that GILT was overexpressed in RA patients (see particularly, page 167, column 2) and noted that "it is striking" that GILT colocalizes in APCs with intracellular MHC Class II molecules (see particularly, page 170, column 1).

Godkins et al. (2001) teaches the routine purification of MHC Class II antigenic peptides comprising the lysing of MHC Class II expressing cells, the isolation of MHC Class II/antigenic peptide complexes, and the subsequent purification of the peptides from said complexes (see particularly, page 6721, *Purification of naturally produced HLA class II molecules and Pool Sequencing*).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to provide a complex of the peptide comprising the amino acid sequence of SEQ ID NO:49 further comprising an MHC Class II molecule for the identification and study of the peptide and its possible role in the pathogenesis of RA given the teachings of Jüsten et al., that "it is striking" that GILT colocalizes in APCs with intracellular MHC Class II molecules, employing the routine method of Godkins et al. The ordinarily skilled artisan would have been interested in the peptide of SEQ ID NO:49 as a candidate MHC class II antigenic peptide particularly in light of the teachings of Jüsten et al.

Applicant argues that as Arunachalam et al. is deficient the rejection must be withdrawn.

See the Examiner's response in Section 4, above

Applicant argue a lack of motivation to make a complex of MHC class II and the peptide of claim 1.

Claim 14 does not recite a "complex". The claim recites an MHC class II molecule linked to the peptide of Claim 1. And note that "linked" is not defined in the specification. Accordingly, said MHC and peptide are shown to be "linked" in some functional sense through their intracellular colocalization as is taught by Jüsten et al.

7. No claim is allowed.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ram Shukla, can be reached on (571) 272-0841.

10. **Please Note:** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR

Art Unit: 1644

or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). Additionally, the Technology Center receptionist can be reached at (571) 272-1600.

/G.R. Ewoldt/
G.R. Ewoldt, Ph.D.
Primary Examiner
Technology Center 1600